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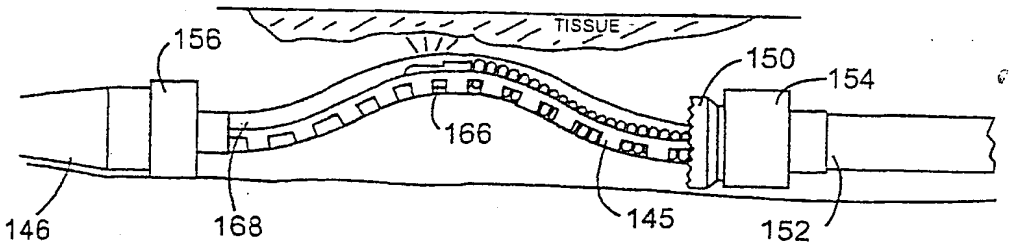


(57) Abstract: Catheters (140), kits, and methods are provided for removing material from a body lumen. The catheters, and methods may be used in a variety of body lumens; including but not limited to coronary, and other arteries. The catheter (140) has a catheter body (142) coupled to a distal sliding tip (146). The sliding tip (146) extends distally between a retracted position, and an extended position to define an adjustable cutting window (148) to receive material to be removed from the body lumen. The catheter (140) has a rotatable cutting element (150) positioned between the distal tip (146), and the catheter body to sever material received in the cutting window (148). Axial movement of the rotating cutting element (150) can sever the material received by the cutting window (148). In some embodiments the rotating cutter (150) is movable outward from the catheter body (142) to engage, and sever material in the body lumen.

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# ATHERECTOMY CATHETER WITH A ROTATING AND TELESCOPING CUTTER

## CROSS-REFERENCES TO RELATED APPLICATIONS

The present application is a continuation-in-part of Application Serial No. 09/387,282, filed August 31, 1999 the complete disclosure of which is incorporated herein by reference. The present application is also related to Application Serial No. 09/378,224, filed August 19, 1999, and Application Serial No. 09/377,884, filed August 19, 1999, the complete disclosure of which is incorporated herein by reference.

## BACKGROUND OF THE INVENTION

The present invention relates generally to apparatus and methods for removing occluding materials from body lumens. More particularly, the present invention relates to the construction and use of atherectomy catheters having a rotating and telescoping cutter.

Cardiovascular disease frequently arises from the accumulation of atheromatous material on the inner walls of vascular lumens, particularly arterial lumens of the coronary and other vasculature, resulting in a condition known as atherosclerosis. Atherosclerosis occurs naturally as a result of aging, but may also be aggravated by factors such as diet, hypertension, heredity, vascular injury, and the like. Atheromatous and other vascular deposits restrict blood flow and can cause ischemia which, in acute cases, can result in myocardial infarction. Atheromatous deposits can have widely varying properties, with some deposits being relatively soft, fibrous, and/or calcified.

Atherosclerosis can be treated in a variety of ways, including drugs, bypass surgery, and a variety of catheter-based approaches which rely on intravascular widening or removal of the atheromatous or other material occluding a blood vessel. Of particular interest to the present invention, a variety of methods for cutting or dislodging material and removing such material from the blood vessel have been proposed, generally being referred to as atherectomy procedures. Atherectomy catheters intended to excise material from the blood vessel lumen generally employ a rotatable and/or axially translatable cutting blade which can be advanced into or past the occlusive material in order to cut and separate such material from the blood vessel lumen. For example, U.S. Patent No. 4,979,951 issued to Simpson, describes a side cutting atherectomy catheter including a housing having a cutting window on

one side, a blade which is rotated and translated by the window, and a balloon that urges the window against the material to be removed.

Although atherectomy catheters have proven to be very successful in treating many types of atherosclerosis, existing catheter designs may be further improved to provide enhanced performance. For example, many side-cutting atherectomy catheters have difficulty in capturing large amounts of occluding material in the cutting window. To improve material capture, it would be desirable to lengthen the cutting window to increase the area into which the material can intrude. Lengthening of the cutter window, however, would require a longer rigid segment at the distal end of the catheter, making it more difficult to advance the catheter through the small, tortuous paths of the vasculature without damaging the body lumen.

For these reasons, it is desired to provide intravascular atherectomy catheters having rigid cutter sections at their distal ends which can travel through the tortuous regions of the vasculature without damaging the body lumen. It is further desirable that the cutting window be adjustable to engage and sever large amounts of material. It would still further be desirable to provide atherectomy catheters which can adjust the length of the rigid region. At least some of these objectives will be met by the catheter and method of the present invention described hereinafter and in the claims.

## SUMMARY OF THE INVENTION

The present invention provides catheters, kits, and methods for removing material from a body lumen. More particularly, the present invention provides an atherectomy catheter having a rotating and telescoping cutter. The atherectomy catheter further includes a sliding distal tip which can extend and retract to provide a rigid distal portion and a cutting window having adjustable lengths.

In a first aspect, the present invention provides a catheter for removing material from a body lumen. The catheter includes a catheter body having a proximal end and a distal end. A guide shaft extends axially through at least a portion of the catheter body. A movable tip is coupled to the distal portion of the guide shaft such that a space between the movable tip and the catheter body defines an adjustable cutting window. A rotatable cutter is movably disposed within the cutting window such that material targeted for removal will intrude into the cutting window and will be severed off when the rotating cutter moves axially within the cutting window.

In one exemplary embodiment, the guide shaft is shaped in a non-linear configuration such that the cutter can be directed out of the catheter body and toward the vessel wall to remove a large amount of material from the body lumen.

In another embodiment, the catheter of the present invention optionally has a material imaging device such as in IVUS. The imaging device may be disposed within a cutting window inside of the guide shaft or on the cutter itself. The imaging device allows the user to interrogate the target area prior to actuation of the cutter.

In another embodiment, a catheter of the present invention optionally comprises a tissue collection chamber disposed in the distal tip. After the material has been severed from the body lumen with the rotating cutter the excised tissue can be packed and stored in the collection chamber.

In another embodiment, the catheter includes a fixed coil tip that can be used to navigate the catheter through the body lumen. The fixed coil tip typically has a lumen that can receive a guidewire. Consequently, a guidewire can be inserted through the lumen in the coil tip to help navigate the catheter.

In yet another aspect, the present invention provides an atherectomy catheter comprising a catheter body having a proximal end and a distal end. A rotatable and translatable cutting element is movably coupled to the distal end of the catheter body and a slidable tip is coupled to the distal end of the catheter body. A gap between the sliding tip and the distal end of the catheter body defines an adjustable cutting window which can receive material to be removed. The cutting element translates between a first position and a second position within the cutting window. When the cutting element moves toward the second position, the cutting element can sever the material that extends into the cutting window.

In a further aspect, the present invention provides a method for removing material from within a body lumen. The method comprises positioning a catheter in the body lumen, usually with the tip of the catheter in a retracted position in the catheter. When the catheter reaches its desired position a cutting window receives the material to be removed and the material is then severed with a rotating and axially moved cutter.

In an exemplary embodiment, the axially movable cutter is directed outside of the catheter body and toward the material within the body lumen. Because the catheter can be disposed against the opposite side of the body lumen when the cutter is directed into the material, no balloon or other biasing device is typically needed to bias the cutter toward the material.

In another exemplary embodiment, the catheter severs the material by distally sliding the cutting element through the material. The excised material can then be packed in a distally located collection chamber.

In yet another aspect, the present invention provides a kit. Kits according to the present invention will comprise a catheter having a rotating and axially translatable cutter. The kits will further include instructions for use setting forth a method as described above. Optionally, the kits will further include packaging suitable for containing the catheter and the instructions for use. Exemplary containers include pouches, trays, boxes, tubes, and the like. The instructions for use may be provided on a separate sheet of paper or other medium. Optionally, the instructions may be printed in whole or in part on the packaging. Usually, at least the catheter will be provided in a sterilized condition. Other kit components, such as a guidewire or an imaging element, may also be included.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of an atherectomy catheter constructed in accordance with the principles of the present invention;

Fig. 2A shows an embodiment of the atherectomy catheter in a closed position;

Fig. 2B shows an embodiment of the sliding tip catheter in an open position;

Fig. 2C shows an embodiment having a penetrating point on the sliding tip;

Fig. 2D shows an embodiment having a sliding tip that slides over the catheter body;

Fig. 2E shows the embodiment of Fig. 2D in an open position;

Fig. 3A shows an embodiment of a sliding tip catheter having a material imaging device positioned below the material to be captured;

Fig. 3B shows the embodiment of Fig. 3A engaging the material;

Fig. 3C shows an embodiment of a sliding tip catheter having a material imaging device positioned on the distal end of the catheter body;

Fig. 3D shows the embodiment of Fig. 3C engaging the material;

Fig 4 shows an embodiment having a plurality of penetrating points;

Fig. 5A is a plan view of an embodiment of the catheter having a material capture device;

Fig. 5B is a cross-sectional view along line 5B of the catheter of Fig. 5A;

Figs. 6-9 are cross-sectional views of a telescoping cutter having a material capture device according to the present invention;

Figs. 10A-10D illustrate a method of the present invention; and

Fig. 11A shows a cross sectional view of a catheter having a rotating and telescoping cutter;

Fig. 11B shows a cross sectional view of a tip ring along line A-A;

Fig. 12 shows the telescoping cutter in a closed position;

Fig. 13 shows the telescoping cutter forming the cutting window;

Fig. 14 shows the cutter moving distally across the cutting window;

Fig. 15 shows the cutter in a distal end of its stroke;

Fig. 16 shows a catheter having a guidewire extending through a guide shaft as the catheter is advanced through a body lumen;

Fig. 17 illustrates an imaging element positioned within the guide shaft;

Fig. 18 illustrates the cutter rotating and telescoping distally to sever atheromatous material from the body lumen;

Fig. 19 shows the severed atheromatous material being collected in a tip collection chamber;

Figs. 20-23 show catheters having a guiding collar/shoe and an axially movable cutting element;

Figs. 24A and 24B show an alternative embodiment of the shoe;

Figs. 25-29 show a catheter having a shaped guide shaft;

Fig. 30 shows an alternative shaped guide shaft;

Figs. 31-36 show another alternative embodiment of catheter having a shaped guide shaft; and

Fig. 37 shows a kit according to the present invention.

## DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention is generally directed to excising material from a body lumen. More particularly, the present invention provides catheters, methods, and kits which have a rotatable and slidable cutter to excise material from the body lumen.

Apparatus according to the present invention will comprise catheters having catheter bodies adapted for intraluminal introduction to the target body lumen. The dimensions and other physical characteristics of the catheter bodies will vary significantly

depending on the body lumen which is to be accessed. In the exemplary case of atherectomy catheters intended for intravascular introduction, the catheter bodies will typically be very flexible and suitable for introduction over a guidewire to a target site within the vasculature. In particular, catheters can be intended for "over-the-wire" introduction when a guidewire lumen extends fully through the catheter body or for "rapid exchange" introduction where the guidewire lumen extends only through a distal portion of the catheter body or the sliding distal tip. In other cases, it may be possible to provide a fixed guidewire at the distal tip of the catheter or even dispense with the guidewire entirely. For convenience of illustration, guidewires will not be shown in all embodiments, but it should be appreciated that they can be incorporated into these embodiments.

Catheter bodies intended for intravascular introduction will typically have a length in the range from 50 cm to 200 cm and an outer diameter in the range from 1 French (0.33 mm; Fr.) to 12 Fr., usually from 3 Fr. to 9 Fr. In the case of coronary catheters, the length is typically in the range from 125 to 200 cm, the diameter is preferably below 8 Fr., more preferably below 7 Fr., and most preferably in the range from 2 Fr. to 7 Fr. Catheter bodies will typically be composed of an organic polymer which is fabricated by conventional extrusion techniques. Suitable polymers include polyvinylchloride, polyurethanes, polyesters, polytetrafluoroethylenes (PTFE), silicone rubbers, natural rubbers, and the like. Optionally, the catheter body may be reinforced with braid, helical wires, coils, axial filaments, or the like, in order to increase rotational strength, column strength, toughness, pushability, and the like. Suitable catheter bodies may be formed by extrusion, with one or more lumens being provided when desired. The catheter diameter can be modified by heat expansion and shrinkage using conventional techniques. The resulting catheters will thus be suitable for introduction to the vascular system, often the coronary arteries, by conventional techniques.

The sliding tip of the catheters of the present invention may have a wide variety of forms and structures. The sliding tips will often be configured so that they may be partially or fully retractable within the distal end of the catheter body in order to permit the length of the distal end of the catheter to be selectively extended and retracted. The sliding tip and/or the distal end of the catheter body will be further configured so that distal advancement of the sliding tip will open a cutting window which will be able to receive or invaginate luminal material to be removed, typically atheroma, thrombus, and plaque from the vasculature. The sliding distal tip is typically conical, cylindrical, or tubular and often has an atraumatic distal end which permits the catheter to be forwardly advanced within the blood

vessel or other body lumen. The sliding distal tip can slide inside the distal end of the catheter, slide over the distal end of the catheter body, or can slide completely separate from the distal end of the catheter body. Typically, the distal tip will have a guidewire lumen to permit the catheter to be advanced over a guidewire, particularly for intravascular deployment. In the exemplary embodiments, the distal end of the catheter body will also be tubular and have a forward-facing circular aperture which receives the sliding tip or a guide shaft therein. Both the sliding tip and the distal end of the catheter body will usually be formed from materials which are rigid or which have very low flexibilities, such as metals, hard plastics, or the like. Most usually, the distal tip and distal end of the catheter body will be formed from stainless steel. The length of the sliding tip may vary widely, typically being in the range from 10 mm to 40 mm, more usually from 20 mm to 30 mm, and preferably in the range from 24 mm to 28 mm. The width of the distal tip will usually be about the same as the catheter body, usually being slightly less to permit telescopic positioning of the distal tip within the opening at the distal end of the catheter body.

A cutter or other cutting element may be disposed at the distal end of the catheter or sliding tip to sever material which is received within the cutting window defined between the distal tip and the catheter body. In an exemplary embodiment, the cutter is movably positioned between the distal end of the catheter body and the distal tip. A cutting blade or other element can be formed integrally with the distal tip and/or the distal end of the catheter body. The use of integral cutting blades and elements allows severing to be effected by simply closing or proximally retracting the sliding distal tip after the material to be removed has been received in the cutting window. Alternatively, the cutting blade or other element can be provided as part of a cutting mechanism which is separate from the catheter body or sliding distal tip. That is, a separate cutting blade can be provided which is separately actuatable and which can sever material received within the cutting window without the need to close the cutting window. For example, the adjustable length atherectomy catheters of the present invention could employ rotatable, axially movable or other separate cutting blades of the type described in U.S. Patent Nos. 5,674,232; 5,242,460; 5,312,425; 5,431,673; and 4,771,774, the full disclosures of which are incorporated herein by reference.

In the exemplary embodiments, the cutting elements are formed as co-axial cylindrical or tubular blades with the cutting edges defined in aligned apertures therein. It will be appreciated that the present invention is not limited to such preferred cutting blade assemblies, in a variety of other designs, such as the use of wiper blades, scissor blades or the

like. Optionally, the cutting edge of either or both the blades may be hardened, e.g., by application of a coating. A preferred coating material is a chromium based material, available from ME-92, Inc., which may be applied according to manufacturer's instructions.

The present invention may optionally employ any of a wide variety of conventional imaging devices and transducers. It will be particularly useful with ultrasonic transducers, such as an IVUS, of a type which may be deployed linearly or circumferentially on the cutting blade. Linear deployment will allow viewing along a discrete length of the catheter axis, preferably adjacent to the cutting point, usually over a length in the range from 1 mm to 30 mm, preferably 2 mm to 10 mm. Circumferentially deployed phased arrays may subtend a viewing arc in the range from 5° to 360°, usually from 180° to 360°. The ability to image over a full 360° can be achieved with the catheters having cutting blades which extend fully from a fixed portion of the cutter assembly, such as those illustrated in Figs. 3A-4. For imaging transducers located on cutting blades within a housing or second cutting element, the field of imaging will generally be limited by the dimensions of the aperture. In some cases, however, it might be possible to fabricate all or a portion of the cutter blade/housing out of an ultrasonically translucent material. In addition to ultrasonic array transducers, the imaging devices of the present invention may comprise optical coherence tomography devices, such as described in U.S. Patent No. 5,491,524, the full disclosure of which is incorporated herein by reference, as well as Huang et al. (1991) Science 254:1178-1181; Brezinski et al. (1997) Heart 77:397-403; and Brezinski et al (1996) Circulation 93:1206-1213. In some instances, the present invention may also provide optical imaging using optical wave guides and the like.

The present invention may also optionally employ any of a wide variety of capture devices to engage and tension the material prior to severing the material from the body lumen. Preferably, the material capture device tensions the material during cutting, reduces the amount of cutting force required, and draws the material into the catheter body after the material has been severed. The capture device can be formed integrally with the distal tip or can be provided separate from the catheter.

Referring now to Fig. 1, a catheter 10 constructed in accordance with principles of the present invention, comprises a catheter body 12 having a proximal end 14 and a distal end 16. In the embodiment shown in Fig. 1, a sliding tip 18 is mounted on the distal end of the catheter body 16 and is slidable in the directions of arrow 19. The sliding tip 18 may be spaced apart from the catheter body to define an adjustable cutting window 22. A cutting element can be integral with the catheter or a separate part of the catheter. Typically,

the cutting element is mounted on the sliding tip 18 and/or on the distal end of the catheter body 16 to sever the material from the body. Preferably, the sliding tip 18 has an atraumatic distal tip 24 to facilitate the introduction of the catheter through a patient's vasculature. A proximal hub 30 is attached to the proximal end of the catheter body and comprises a perfusion/aspiration connector 32, a guidewire connector 34, a slider 36, and an imaging element interface (not shown). Preferably, a "monorail" guidewire lumen design can be used in which the lumen only spans the atraumatic tip. Alternatively, a guidewire 35 can be extended through the guidewire connector 34 and catheter body to the sliding tip 18 to facilitate advancement through the vasculature. The slider 36 is attached to the proximal end of an actuator rod 37 which extends from the hub 30 through the lumen of catheter body 12 to the sliding tip 18 where it is attached at a proximal end of the sliding tip 18. In this way, manual actuation of slider 36 in the directions of arrow 38 moves the sliding tip 18 in the directions of arrow 19.

The catheter 10 is quite useful and an improvement over conventional atherectomy catheters. The decrease in the rigid portion 23 of catheter 10 is a significant advantage, particularly when the catheter is introduced to the highly tortuous regions of the coronary vasculature. Once at a desired location, however, the rigid sliding tip 18 can be extended in length by 50% or more, with a theoretical limit of 100% for a two-portion sliding region. Another useful aspect of the present invention is the adjustable cutting window 22. The cutting window can be enlarged by moving the sliding tip toward the fully extended position. This allows the user to adjust the cut size to the length of the lesion to be treated. Typically, the cutting window 22 will have at least one cutting element. Conventional atherectomy devices typically require a balloon or other biasing device. In contrast, the telescoping catheters of the present invention do not require use of a balloon since the shaped guide tube provides an invagination force to effectively move the cutter into position to remove material from the body lumen. In alternative embodiments, it will possible for the cutting window to have two cutting blades and/or a variety of configurations. While the cutting blades will preferably employ the cutting edges at each end of the cutting window 22, the advantages of the sliding tip 18 can be enjoyed with only one cutting edge or even without the cutting edges.

Figs. 2A-2C illustrate some embodiments incorporating the present invention. Fig. 2A shows the distal sliding tip 18 in a retracted position relative to the catheter body 12. A sharpened proximally-facing edge of the sliding tip 18 is substantially contained within the catheter body 12 and the rigid portion 23 of the catheter is minimized. In this position, the

catheter can be advanced through the tortuous vasculature without damaging the body lumen with an exposed cutting element and/or an edge of the cutting window. As shown in Fig. 2B the catheter may have a first cutting element 20 on the sliding tip 18 and a second cutting element 21 on the catheter body. Alternatively, as shown in Fig. 2C, the cutting elements 18 can have a penetrating point 52 to facilitate the removal of the material from the body lumen. Figs. 2B and 2C show the sliding tip 18 extending out of a forward-facing distal aperture 25 on the catheter body. The gap between the distal end of the catheter body 12 and the cutting element defines the side-opening cutting window 22. Cutting window 22 and rigid portion 23 can be increased and decreased in size by moving the sliding tip between the extended position (Fig. 2B) and retracted position (Fig. 2A). Material intruding into the cutting window is preferably severed off by moving the sliding tip from its extended position to the retracted position. Alternatively, the material can be severed with a wholly separate cutting element while the sliding tip remains in the extended position. It will be appreciated that any combination of cutting elements can be used to sever the material from the body lumen.

Figs. 2D and 2E illustrate another embodiment of the present invention. Fig. 2D shows the distal sliding tip 18 in a retracted position over the distal end 16 of the catheter body 12. In this position, the cutting window 22 is covered by the sliding tip 18 and the catheter can be advanced through the tortuous vasculature without damaging the body lumen with an exposed cutting element. Once the catheter has been advanced to a desired position, the sliding tip 18 will be advanced distally over the distal end 16 of the catheter body to expose the cutting window 22. Similar to the above embodiments, the distal end of the catheter and/or the sliding tip may comprise cutting elements to help facilitate the severing process.

Figs. 3A and 3B illustrate an embodiment having material imaging devices positioned on the catheter. As shown in Fig. 3A, atraumatic distal tip 24 can be equipped with a material imaging device such as an array of ultrasound transducers or an optical coherence tomography device. Some preferred embodiments have the imaging device rotating inside the guide tube or rotating with the cutter. Such embodiments allow the body lumen to be imaged simultaneously with tissue removal as the catheter is advanced through the body lumen. In other embodiments, a fixed or rotating single transducer may be used to provide imaging. The material imaging device 50 can provide images when the sliding tip 18 is in a retracted position as shown in Fig. 3A or in an extended, material-engaging position as shown in Fig. 3B. As best seen in Fig. 3A, when the sliding tip 18 is retracted, the imaging device 50 will lie adjacent to the leading edge of the catheter body 12, where the catheter

body acts as the second blade to effect severing of the material. Thus, the material imaging device 50 will be positioned in the body lumen right at the point where material M will be severed. The cutting element 20 as shown in Fig. 3B, typically includes a penetrating point 52 to facilitate material M capture. By locating the material imaging device 50 on the sliding tip 18, the present invention can move the imaging device through the various paths or cutting zones if the cutting blade is actuated. This ability to move the imaging device 50 allows for imaging and cutting of the targeted material without having to reposition the catheter body 12 which may cause misalignment of those materials imaged before cutting and the actual location of the cutting zone. Of course, the material imaging device 50 can be used at any point during the procedure, either before or after severing of the target material and an image can be produced even while the cutting blade is being moved between the retracted and extended positions of the sliding tip 18.

As shown in Figs. 3C and 3D, instead of having the material imaging device 50 positioned on the sliding tip 18, the material imaging device 50 can also be positioned on the catheter body 12 to image the material to be removed. There are certain advantages to positioning the imaging device 50 on the catheter body 12. First, the overall cutting procedure with this device may be accomplished by crossing the lesion with the device and then cutting the lesion while pulling the catheter back. Using this technique, an imaging device 50 on the catheter body 12 would provide images of the tissue just before it is encountered by the cutting element. Second, an imaging device 50 on the catheter body 12 would not reciprocate and thus may provide an image that would be easier for the user to interpret during the actual cutting process. Finally, an imaging device 50 on the catheter body 12 would be easier to manufacture than one on the reciprocating tip 18. This is because the wiring or fibers leading to the element would not have to flex with respect to the element and could be fixedly attached to the catheter body 12.

The cutting edge 20 on the cutting blade 18 may be designed to have a plurality of penetrating points 32 as shown in Fig. 4 or the distal end of the catheter body can be formed to have a corresponding cutting blade which fittingly receives the penetrating point of the cutting blade 18. Suitable cutting blades and cutting edge designs can be found in commonly assigned co-pending U.S. Patent Application No. 08/982,231 (Attorney Docket No. 18489-000200US) filed on December 17, 1997, which is incorporated herein by reference.

Figs. 5A and 5B show a catheter 70 having a telescoping distal tip 18 and a material capture needle 74 to capture the material and tension it towards the cutting elements

20, 21. The material capture needle 74 follows a path where the material capture needle extends outwardly from the cutting window and moves inwardly towards the catheter body to tension the material. Similar to above embodiments, the telescoping, sliding tip 18 can decrease the rigid length of the catheter 23 and can create a larger window or aperture 22 for removing greater amounts of material. In this embodiment, when the material capture needle 74 is deployed, it angles out from the cutting window 22 and a portion of the material capture needle typically runs parallel to the window with the sharpened tip located near the distal end of the cutting window. The cutting element 20 is reciprocated to open and close the cutting window 22 formed between the sliding tip 18 and the catheter body. Movement of the sliding tip 18 also controls the deployment and retraction of the material capture needle. When the sliding tip 18 opens the window 22, the material capture needle 74 is biased outwardly from the catheter body. The material capture needle 74 is preferably spring-loaded, where in its resting condition, the material capture needle extends outwardly from the catheter body. The material capture needle 74 is otherwise constrained within the catheter body when the sliding tip 18 closes window 22. As the sliding tip 18 is drawn proximally toward its retracted position, the material capture needle 74 will be pushed into the cutting window 22 as indicated by arrow 78, along with material attached to the material capture needle. As the material capture needle is pushed into the cutting window, the material will be drawn into the catheter body and tensioned prior to being severed. As seen in Fig. 5B, the material capture device 74 may also include one or more barbs 79 which keep the material from sliding off once it is excised. The material capture needle 74 may be made of a variety of materials such as stainless steel or a superelastic material, such as nickel titanium.

Referring now to Figs. 6-9, an exemplary telescoping cutting device using a material capture device will be described in further detail. As shown in Fig. 6, the telescoping tip 100 in this embodiment of the cutting device extends outwardly from an aperture 102 on the catheter body 104. The catheter body 104 may include a cutting blade 105 for shearing material drawn into the cutting device. It should be understood, of course, that the blade may be located in a variety of positions such as on the telescoping portion 100 of the device or located on both the telescoping portion and the catheter body. As shown in Fig. 6, the distal end 106 of the telescoping portion 100 is preferably adapted to mount a soft, atraumatic distal tip 124 (shown in phantom) to facilitate passage of the device through body lumens. In some embodiments, the tip may be integrally formed with the telescoping portion 100. In other embodiments the catheter will be put over a guidewire (not shown) to advance the catheter to the desired position.

As seen in Fig. 6, the telescoping portion 100 is in an extended position where one edge 107 of the telescoping portion is spaced apart from the catheter body and defines a cutting window 108. In some embodiments, the edge 107 may comprise a cutting blade while in other embodiments the edge may be unsharpened, but pushing material into the cutting window. The cutting window 108 is preferably a directional cutting window which may open towards one side of the catheter where material maybe pulled in by penetrating member 110 to be cut off. This penetrating member 110 is preferably rotatably mounted about a pivot pin 112 on the telescoping portion 100 to engage the material. It should be understood that some embodiments of the telescoping portion 100 may not include the penetrating member 110. The penetrating member 110 is shown in Fig. 6 to be in a first, tissue-engaging position. A tether or leash element 114 is rotatably coupled to the penetrating member 110 and can be pulled proximally as indicated by arrow 116 to rotate the member into the tissue-engaging position. The tether 114 may be made of a variety of materials such as stainless steel or a polymer like polyimide or a fibrous material like Kevlar®.

Fig. 7 shows the telescoping portion 100 being manually or automatically retracted by a drive wire 118 as indicated by arrow 120. As one end of the penetrating member 110 contacts abutment or deflection block 122, the penetrating member 110 will begin to rotate as indicated by arrow 124. Further retraction of the telescoping portion 100 will cause the sharpened tip 126 of the penetrating member 110 to be pushed within the boundaries of the catheter body. As seen in Fig. 8, the penetrating member 110 and telescoping portion 100 may be substantially retracted into the catheter body 104. The tether 114 has a bent portion 130 that allows clearance for the penetrating member to be rotated to the position shown in Fig. 9. Retraction of the penetrating member 110 into the catheter body as shown in Fig. 9 also functions to push tissue proximally into the catheter shaft 104 where it can be stored.

Figs. 10A-10D illustrates an exemplary method of the present invention. The catheter 10 is placed in the body lumen while in the retracted position (Fig. 10A). The catheter is advanced through the body lumen to the desired position (Fig. 10B). The sliding tip 18 is then distally advanced to an extended position to open a cutting window 22 to receive the material M to be removed (Fig. 10C). Once the material has invaginated the cutting window 22, the material is severed. Preferably, the material is severed by moving the sliding tip 18 to its retracted position (Fig. 10D). In one method, a cutting element mounted on the sliding tip 18 engages and severs the material as the cutting window 22 is closed. If

the lesion is longer than the window opening, the catheter is pulled back and another cut is made. In alternative methods, the sliding tip 18 merely pushes the material against a cutting element on the distal end 16 of the catheter to sever the material. In yet another method, the material is received in the cutting window 22 and the sliding tip stays in an extended position while a separately translatable cutting element severs the material from the body lumen.

In another aspect, the present invention provides a catheter having a rotatable and axially translatable cutter. As illustrated in Figs. 11A-15, the catheter 140 generally includes a catheter body 142 having a proximal end (not shown) and a distal end 144. A hollow guide shaft or tube 145 is movably disposed within a lumen of the catheter body 142 and is extendable beyond the distal end 144 of the catheter body to connect to a distal tip 146. Axial movement of the guide shaft 145, typically through manual actuation of an input device, moves the distal tip 146 axially away from the catheter body 142 to create an adjustable cutting window 148. In alternative embodiments, the position of the sliding distal tip can be maintained and the catheter body 142 can be retracted proximally to create the cutting window 148. The cutting window 148 can receive luminal material from within the body lumen. The material received in the cutting window 148 can be severed from the body by a rotatable cutter or cutting element 150. In most configurations, the cutting element is slidably positioned between the distal end 144 of the catheter body and the distal tip 146 such that axial translation of the rotating cutting element from a first position (Fig. 13) to a second position (Figs. 14 and 15) removes any material invaginating the cutting window 148. In an exemplary embodiment the first position is a proximal or retracted position and the second position is a distal or expanded position. In other embodiments, it may be able to move the cutting element from a distal position to a proximal position to sever material.

The catheter 140 preferably has an atraumatic distal tip to facilitate the introduction of the catheter through a patient's vasculature. In some configurations, the catheter 140 includes a fixed coil tip 147 that has a lumen 149 (Figs. 24A and 24B). The coil tip 147 can be used to advance the catheter 140 through the body lumen without a guidewire. In the alternative, a guidewire (not shown) can be inserted through the lumen 149 in the coil tip 147 to help guide the catheter through the body lumen.

A proximal hub (see Fig. 1) is attached to the proximal end of the catheter body and comprises a perfusion/aspiration connector, a slider, a guidewire connector, and/or an imaging element interface. Similar to the above embodiments, a monorail guidewire lumen design can be used in which the lumen only spans the atraumatic tip.

In some embodiments, the cutting element 150 is a sharpened stainless steel cylindrical part that is coupled to a distal end of a wire-reinforced polymer cutter drive shaft 152. Both the cutter 150 and cutter drive shaft 152 are preferably hollow so that both the cutter and cutter drive shaft can rotate and move axially over the guide shaft 146. The proximal end of the cutter drive shaft 145 is connectable to a motor (not shown) that can rotate the cutter drive shaft 152 and cutter 150 between approximately 1000 rpm and 5000 rpm. It should be appreciated however, that the speed of rotation of the cutter will vary depending on the type of material to be removed, the type of body lumen, and the like. It should also be appreciated that in some embodiments both the guide shaft 145 and cutter drive shaft 152 can be flexible to allow the distal tip to follow the curvature of the body lumen.

Most embodiments of the catheter include a stainless steel nest ring 154 positioned on the distal end of the catheter body 142 and a stainless steel tip ring 156 positioned on the proximal end of the distal tip 146. As shown in Figs. 12 and 16, the nest ring 154 and tip ring 156 can be used to encompass the cutter 150 when the catheter 140 is introduced into the body lumen in a closed position. In the closed position (Fig. 12), the rigid length of the catheter can be reduced and the catheter can be advanced through the small, tortuous regions of the body lumen without unduly damaging the body lumen. As an additional benefit of the tip ring, when the rotatable cutter 150 reaches the distal end of its stroke, a cutting edge 158 of the tip ring 156 can help remove the excised material 160 and help direct the removed material into a collection chamber 162 disposed within the hollow distal tip 146. As shown generally in Fig. 11B, the tip ring 156 includes a stainless steel ring 161 which has an opening 163 that allows severed material to enter a polymer or composite cone-shaped collection chamber 162 disposed within the tip 146. The tip ring 156 can further provide support to the guide shaft 145 and tip 146 while allowing severed material to be packed and stored in the collection chamber 162.

The guide shafts 145 of the present invention are preferably hollow so as to be able to receive a guidewire 164 (Fig. 16) and/or an imaging element 166 (Fig. 17). For example, during delivery to the target area, the guidewire 164 can be advanced through the lumen of the guide shaft 145 (Fig. 16). After the catheter 140 has been advanced to the target site, the guidewire 164 can be removed and the imaging element 166 can be advanced through the guide shaft until the imaging element is positioned in an imaging window 168. If it is determined that the cutting window 148 is positioned adjacent the diseased area, the cutter 150 can be rotated and translated to sever the material from the body lumen.

In use, the catheter 140 is delivered percutaneously over a guidewire 164 and through a guiding catheter (not shown) using standard interventional techniques. As shown in Fig. 16, in most embodiments the cutter 150 is nested within the nest ring 154 and the tip ring 156 to reduce the rigid length of the catheter 140. The catheter 140 is advanced to a diseased area of one of the coronary arteries and the catheter body 142 and cutter 150 are moved proximally and/or the tip 146 is moved distally so that the cutting window 148 is created between the cutter 150 and the tip 146. As shown in Fig. 17, the imaging element 166, such as a transducer, can be advanced through the hollow guide shaft 145 and into the imaging window 168 so that the diseased area can be imaged prior to treatment. If it is determined that the catheter and cutting window 148 are positioned adjacent the diseased area, the cutter can be activated. Typically a motor that is coupled to a proximal end of the cutter drive shaft 152 is activated to rotate the cutter. The cutter 150 can be advanced distally to sever the material. Rotation and translation of the cutter 150 can occur simultaneously through actuation of a single input device, or alternatively, the rotation and axial translation of the cutter can be activated with independent input devices. As the rotating cutter 150 and drive shaft 152 are translated axially, the excised tissue can be pushed through the opening 163 in the tip ring 156 into a hollow collection chamber 162 positioned within the tip 146. As the cutter 150 reaches the distal end of its stroke (Fig. 19), the cutting edge 158 of the cutter nests inside the tip ring 154 to part off the excised tissue. This procedure can be repeated until the blockage is reduced within the body lumen to a clinically acceptable level.

In the embodiments illustrated in Figs. 20-23, the cutting element may be coupled to a bearing or shoe 165 that guides the cutting element and protects a non-targeted portion of the body lumen. The bearing 165 can comprise a first opening that receives the rotatable cutting element 150 and a second opening which rides over a guide collar 167. As shown in Fig. 21, the soft tip 146 and part off ring 156 can be telescoped distally to open the cutting window 148. The cutting element 150, drive shaft 152, and shoe 165 are advanced distally to sever the material (not shown) invaginating the cutting window. Because the shoe 165 is keyed to the non-rotating, guide collar 167, the shoe 165 can be advanced without rotation. Consequently, the non-targeted portion of the body lumen can be protected from the rotating cutting element 150. In one configuration shown in Fig. 23, the slotted collar 167 is a molded part that includes wires or the like to provide shape and/or stiffness. The molded collar 167 is coupled to outer sheath 169 and distal tip 146. Actuation of the outer sheath 169 and molded collar 167 telescopes the tip 146 and opens the cutting window 148. In such embodiments, the guide shaft 145 does not have to be attached to the distal tip 146 and can be

moved axially. Similar to the above embodiments, the cutting element 145 can be guided axially with the keyed bearing 165 to sever material invaginating the cutting window. Radiopaque markers 171, 173 can be positioned on the outer sheath 169 or on the tip 146.

In yet another configuration, protective shoes 165a, 165b can be affixed to the distal end of the catheter body and distal tip such that the shoes protect the non-targeted portion of the body lumen when the tip is telescoped distally. In contrast to the other protective shoes, protective shoes 165a, 165b of this embodiment are not coupled to the cutting element 150. As shown in Figs. 24A and 24B, in the telescoped configuration, the protective shoes can at least partially separate the non-targeted portion of the body lumen from the rotating cutting element.

As illustrated in Figs. 25-29, in another aspect of the present invention, a distal portion of the guide shafts 145 can be bent or shaped to improve tissue invagination and cutting directionality. The distal bend in the guide shaft can direct the cutting element 150 radially outward from the catheter body to improve tissue capture and directionality of severing.

In one configuration, the distal portion of the shaped guide shaft 145 is bent in a ramp or bump to guide the cutting element outward from the catheter body. It should be appreciated however, that other bends can be used to move the rotating cutting element outward. For example, the guide shaft 145 can be bent to move the entire distal tip off of the longitudinal axis (Fig. 30). In such configurations, a longitudinal axis of the distal tip 146 can be displaced from the longitudinal axis of the catheter body between approximately 0.010 inches and 0.080 inches.

Slots can be laser etched into the guide shaft to improve bending and to maintain a springiness in the guide shaft. To help the guide shaft 145 maintain its bent shape, the guide shaft can be laminated with a polymer. The lamination allows some flexibility in the guide shaft, while preventing the guide shaft from yielding completely. In other configurations, the guide shaft can be composed of a shape retaining material, such as nitinol. The bent distal portion of the guide shaft can be retracted into the catheter body to a semi-straighten configuration. Similarly, the catheter body 142 may achieve a semi-curved configuration to coincide with the shape of the guide shaft 145.

The shaped guide shaft 145 provides improved cutting directionality by allowing the user to direct the cutting element to a specific portion of the body lumen. In use, the distal tip can be telescoped outward to open the cutting window. The shaped guide shaft can expand to its curved configuration (Fig. 25). A viewing window 175 can be created on or

near the bent distal portion to allow the imaging element to view the target tissue. Once it is determined that the catheter is positioned adjacent the target tissue, the cutting element 150 is advanced distally along the shaped guide shaft 145 and directed radially outward from the longitudinal axis of the catheter. Tissue is engaged and severed from the body lumen and pushed downward into the distal collection chamber 162 with the cutting element 150 (Figs. 27-29). To remove tissue from another portion of the body lumen, the body lumen can be viewed with the imaging element 166 and the entire catheter 140 can be rotated until the desired portion of the body lumen is adjacent the bent guide shaft 145. Because the guide shaft directs the cutting element out of the catheter body, the catheter body can be much smaller than the body lumen and still effectively remove material without use of a balloon or other biasing devices. Consequently, less time is need to recanalize the body lumen and a more efficient procedure can be performed.

In another embodiment shown in Figs. 31-36, the catheter can include a flexible outer cover 180. The catheter includes a catheter body having a coil tip 146 and a coiled outer cover 180 that is composed of a single continuous piece of coil. The flexible outer cover provides cutting directionality to the telescoping device and can provide a large distal storage chamber. Similar to the above methods, the guide shaft 145 can be expanded out of the cutting window and moved into close proximity of the material and the rotating, axial moveable cutting element is directed toward the material to sever the material (Figs. 34 and 35). The cutting element 150 severs the material and stores the severed material in a distal storage area (Fig. 36).

Referring now to Fig. 37, the present invention will further comprise kits including catheters 400, instructions for use 402, and packages 404. Catheters 402 will generally be as described above, and the instructions for use (IFU) 402 will set forth any of the methods described above. Package 404 may be any conventional medical device packaging, including pouches, trays, boxes, tubes, or the like. The instructions for use 402 will usually be printed on a separate piece of paper, but may also be printed in whole or in part on a portion of the packaging 404. Usually, at least the catheter will be provided in a sterilized condition. Other kit components, such as a guidewire, imaging devices, or the like may also be included.

While the above is a complete description of the preferred embodiments of the inventions, various alternatives, modifications, and equivalents may be used. For example, while the rotatable and telescoping cutter is shown severing material as the cutter moves distally, it should be appreciated that the catheter can be modified such that proximal

movement of the cutter sever material from the body lumen and forces the severed material proximally down the catheter body. The rotating and telescoping cutter may be coupled with the distal tip such that distal movement of the cutter and distal tip creates the cutting window and proximal movement of the rotating cutter severs the material from the body lumen.

Although the foregoing has been described in detail for purposes of clarity of understanding, it will be obvious that certain modifications may be practiced within the scope of the appended claim.

WHAT IS CLAIMED IS:

1. A catheter for removing material from a body lumen, the catheter comprising:

a catheter body defining a longitudinal axis, a proximal end, and a distal end;

a movable guide shaft extending axially through at least a portion of the catheter body;

a movable tip coupled to a distal portion of the guide shaft, wherein a space between the tip and the catheter body defines an adjustable cutting window; and

a rotatable cutter axially movable within the cutting window to sever material that is received in the cutting window.

2. The catheter of claim 1 wherein a distal portion of the guide shaft is shaped so as to move the rotatable cutter outward from the longitudinal axis and toward the material in the body lumen.

3. The catheter of claim 2 wherein distal movement of the tip and guide shaft relative to the catheter body creates the cutting window.

4. The catheter of claim 1 wherein the tip comprises a fixed coil tip.

5. The catheter of claim 4 wherein the fixed coil tip comprises a lumen that can receive a guidewire.

6. The catheter of claim 1 wherein proximal movement of the catheter body and cutter creates the cutting window.

7. The catheter of claim 1 wherein the rotatable cutter moves independently of the movement of the tip.

8. The catheter of claim 1 wherein the tip comprises a collection chamber that can receive excised tissue.

9. The catheter of claim 1 wherein the cutter is coupled to a motor through a cutter drive shaft

10. The catheter of claim 9 wherein the cutter drive shaft rides over the guide shaft.

11. The catheter of claim 9 wherein the motor rotates the cutter drive shaft and rotatable cutter between approximately 1000 rpm and 5000 rpm.

12. The catheter of claim 1 wherein the tip comprises a tip ring that at least partially encloses the rotatable cutter when the tip is in the second position.

13. The catheter of claim 1 wherein the catheter body comprises a nest ring disposed at the distal end of the catheter body, wherein the nest ring at least partially encloses the rotatable cutter when the cutter is in the first position.

14. The catheter of claim 1 wherein the guide shaft is hollow, wherein the guide shaft can receive at least one of an imaging element and a guidewire.

15. The catheter of claim 14 wherein the guide shaft comprises an imaging window so that the imaging element can image the body lumen through the cutting window.

16. The catheter of claim 1 wherein the guide shaft moves the tip between 0.010 inches and 0.080 inches orthogonal from the longitudinal axis.

17. The catheter of claim 1 further comprising a non-rotating, axially translatable shoe coupled to the cutting element, wherein the shoe translates with the cutting element to protect a non-targeted portion of the body lumen.

18. An atherectomy catheter comprising:

a catheter body comprising a proximal end, a distal end, and a longitudinal axis;

a rotatable and axially movable cutting element movably coupled to the distal end of the catheter body;

a distal slidable tip operatively coupled to the distal end of the catheter body, wherein the tip is movable between a open position and a closed position, wherein the tip in the closed position defines a cutting window;

wherein the cutting element translates between a first position and a second position, wherein the cutting element in the first position allows material to intrude into the cutting window, and wherein the cutting element severs the material extending into the cutting window when the cutting element moves toward the second position.

19. The system of claim 18 wherein the slidable tip is operatively coupled to the catheter body with a guide tube, wherein the guide tube extends outwardly from a distally facing aperture on the catheter body.

20. The system of claim 19 wherein the guide tube is adapted to receive at least one of a guidewire and an imaging element.

21. The system of claim 19 wherein the guide tube comprises an imaging window.

22. The system of claim 19 wherein a distal portion of the guide tube is bent to move the cutting element radially from the longitudinal axis and out of the catheter body to engage and sever the material.

23. The system of claim 19 comprising a axially movable, non-rotating shoe that protects a non-targeted portion of the body lumen from the cutting element.

24. The system of claim 19 wherein a nest ring is positioned on the distal end of the catheter body to receive the cutting element.

25. The system of claim 19 wherein the slidable tip comprises a tissue collection chamber.

26. A method for removing material from within a body lumen, the method comprising:

positioning a catheter in the body lumen;

receiving the material in a cutting window;

rotating and axially moving a cutter from a first position to a second position to sever the material in the cutting window.

27. The method of claim 26 comprising directing the cutter radially out of the catheter.

28. The method of claim 27 wherein directing is carried out by advancing the cutter over a bent guide shaft.

29. The method of claim 26 wherein positioning comprises advancing the catheter through a body lumen with a fixed coil tip.

30. The method of claim 26 comprising protecting a non-targeted portion of a body lumen with a non-rotating shoe that travels with the cutter.

31. The method of claim 26 wherein receiving comprises advancing a tip distally relative to a catheter body to form the cutting window.

32. The method of claim 26 comprising storing the severed material in a collection chamber disposed within a tip of the catheter.

33. The method of claim 26 wherein opening comprises substantially maintaining the position of a tip and moving the cutter and a catheter body proximally.

34. The method of claim 26 wherein positioning comprises reducing a rigid length of the catheter.

35. The method of claim 26 wherein reducing comprises nesting the cutter in a nest ring and a tip ring.

36. The method of claim 26 comprising imaging the body lumen with an imaging element positioned within the cutting window.

37. The method of claim 26 wherein the cutter is positioned between a catheter body and a distal tip.

38. The method of claim 26 comprising biasing a distal tip off of a longitudinal axis of the catheter body.

39. A catheter for removing material from a body lumen, the catheter comprising:

a catheter body defining a longitudinal axis, a proximal end, and a distal end;

a guide shaft extending axially through at least a portion of the catheter body, the guide shaft comprising a shaped distal end;

a tip coupled to a distal portion of the guide shaft, wherein a space between the tip and the catheter body defines an adjustable cutting window; and

a rotatable cutter axially movable within the cutting window to sever material that is received in the cutting window wherein the rotatable cutter moves over the shaped distal end of the guide shaft outward from the longitudinal axis to sever the material from the body lumen.

40. A kit comprising:

a catheter having a slidable cutting element and a movable distal tip which extends from a distal end of the catheter;

instructions for use in removing material from a body lumen comprising positioning the catheter in a body lumen adjacent to material to be removed, distally advancing the distal tip to open a cutting window and receiving the material to be removed, and rotating and advancing the cutting element to sever the material in the cutting window; and

a package adapted to contain the device and the instructions for use.

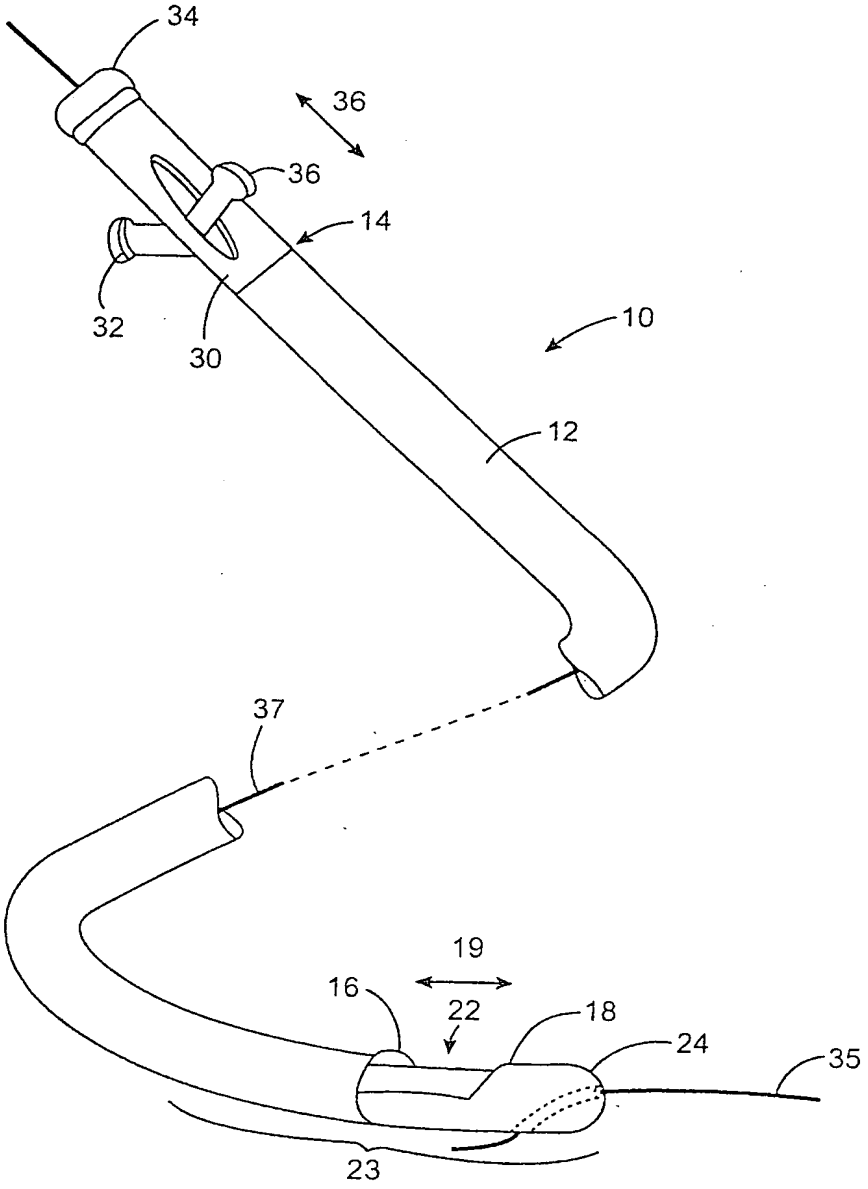



FIG. 1

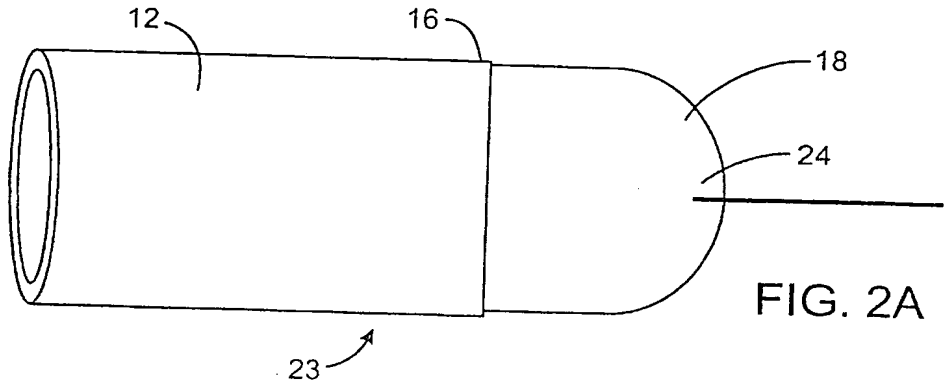



FIG. 2A

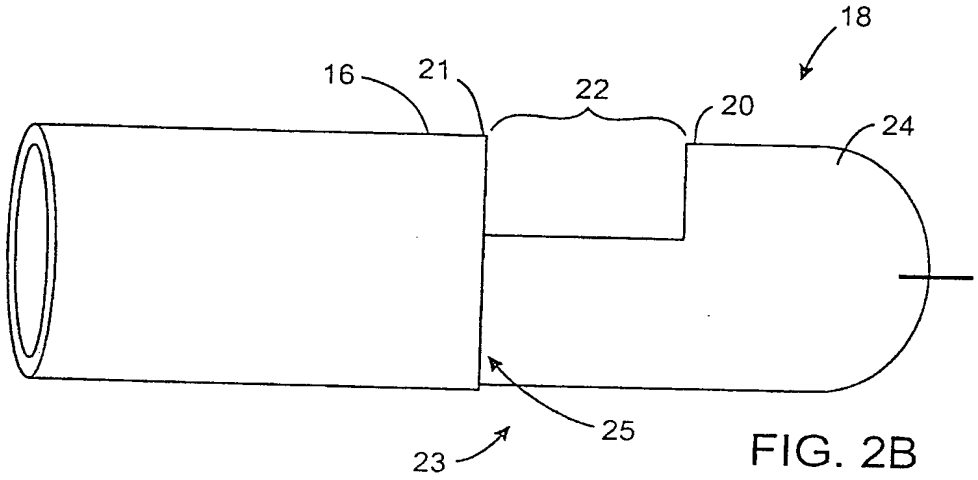



FIG. 2B

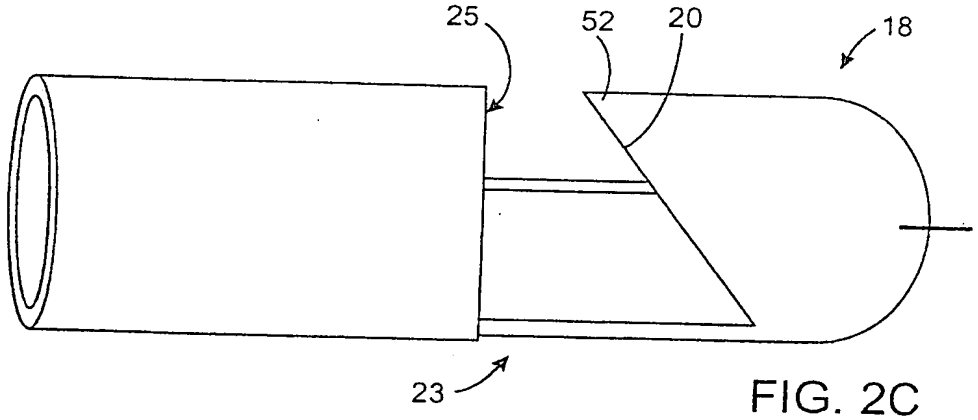



FIG. 2C

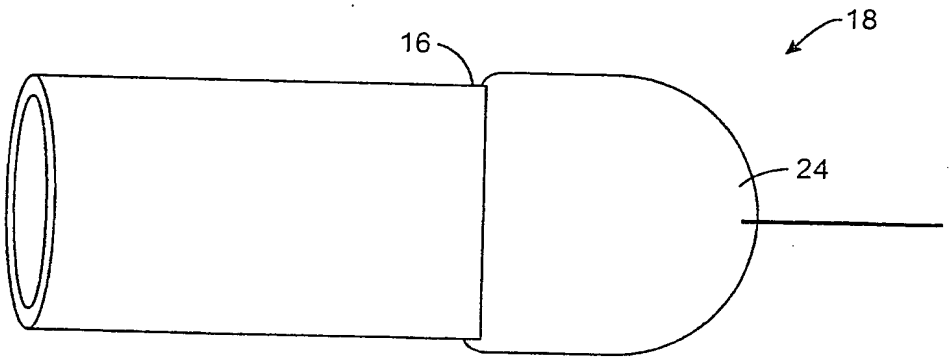



FIG. 2D

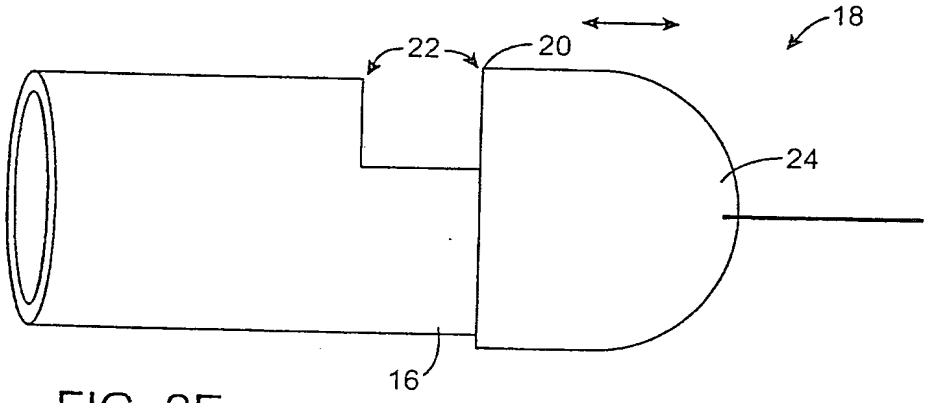



FIG. 2E

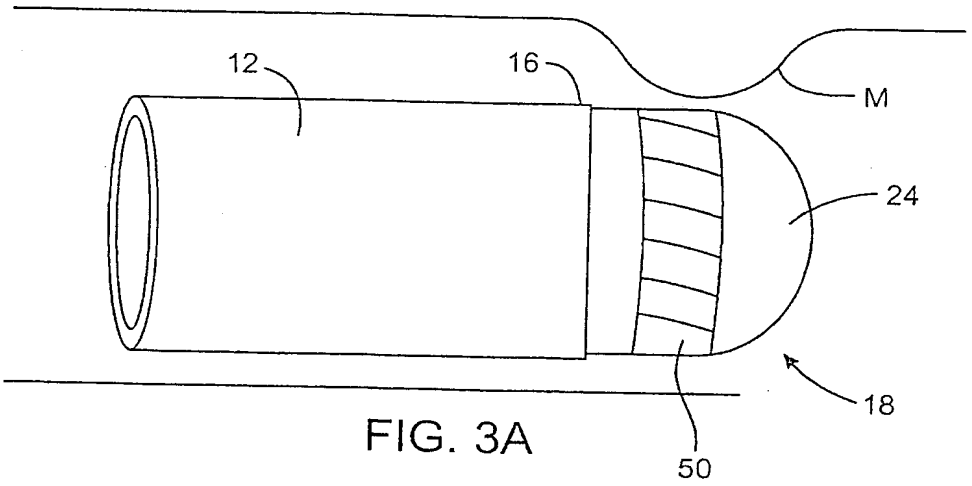



FIG. 3A

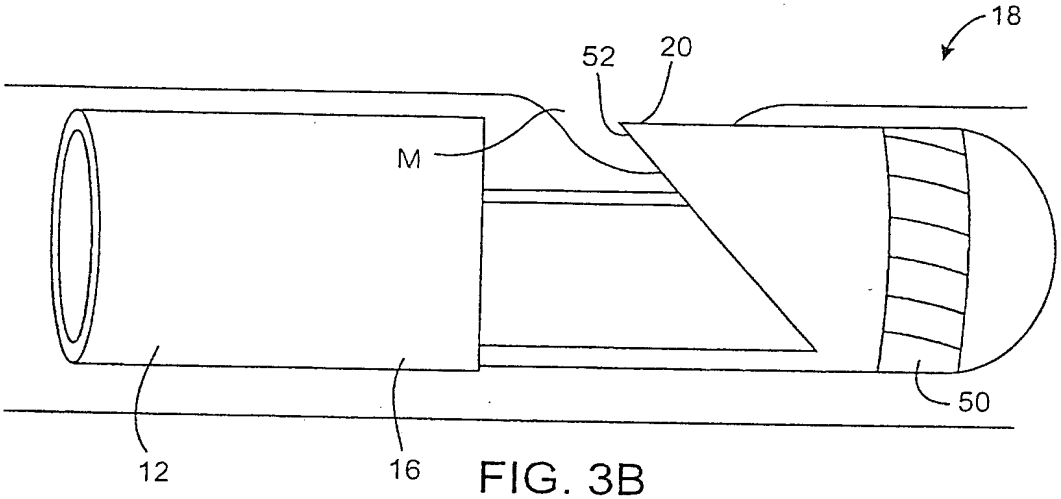



FIG. 3B

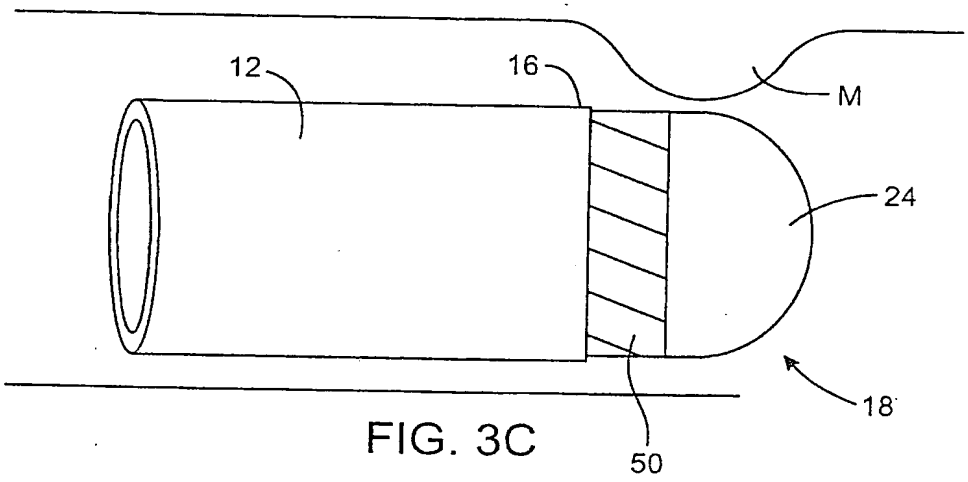



FIG. 3C

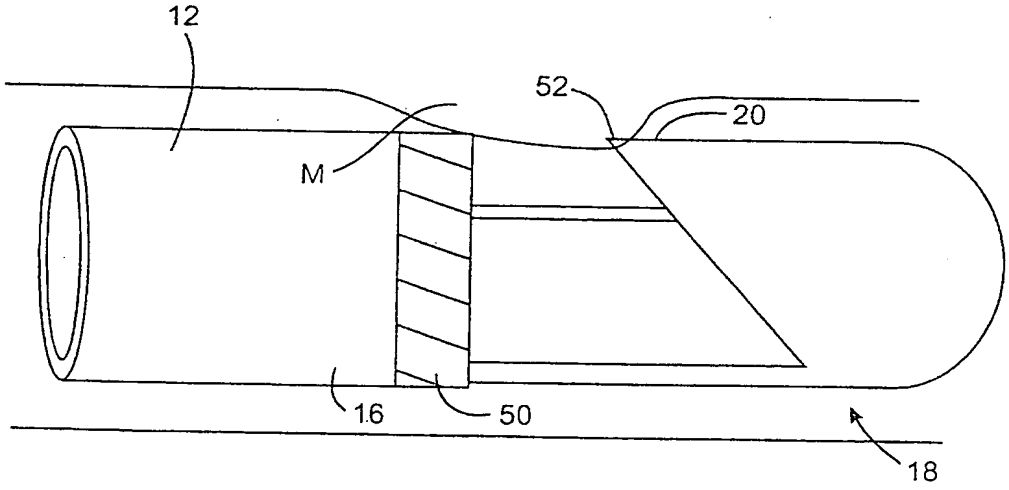



FIG. 3D

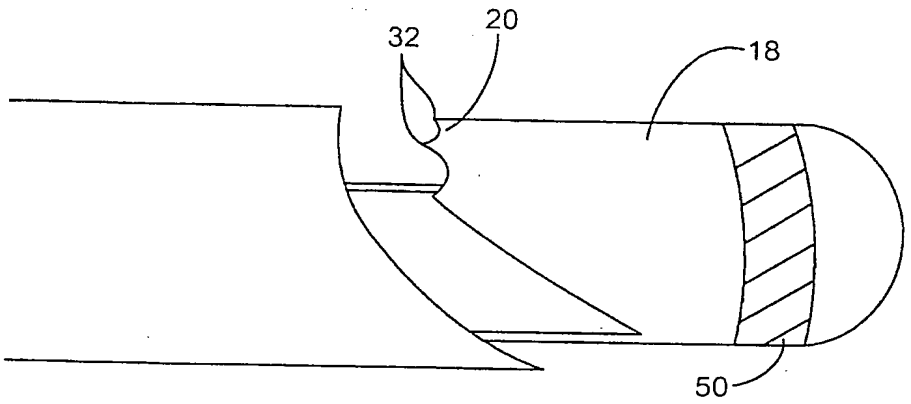



FIG. 4

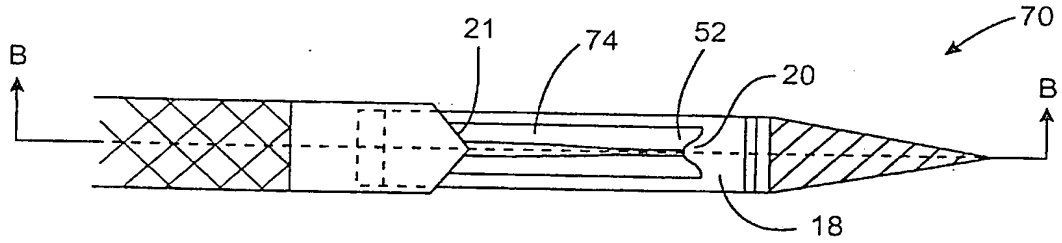



FIG. 5A

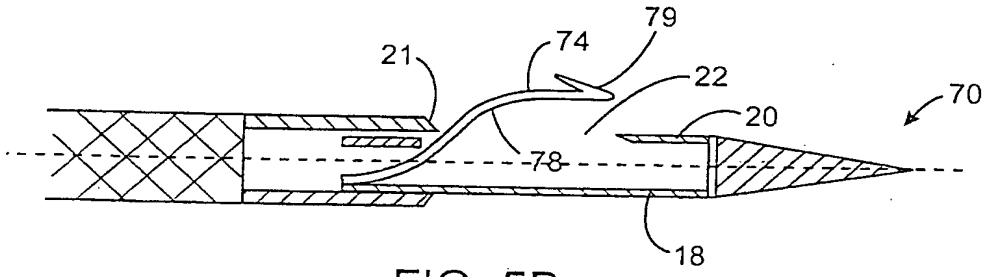



FIG. 5B

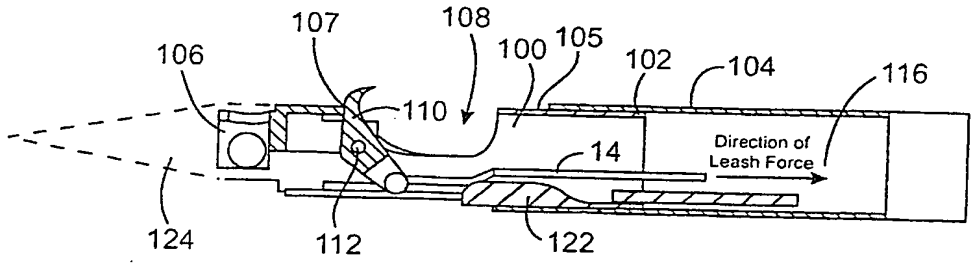



FIG. 6

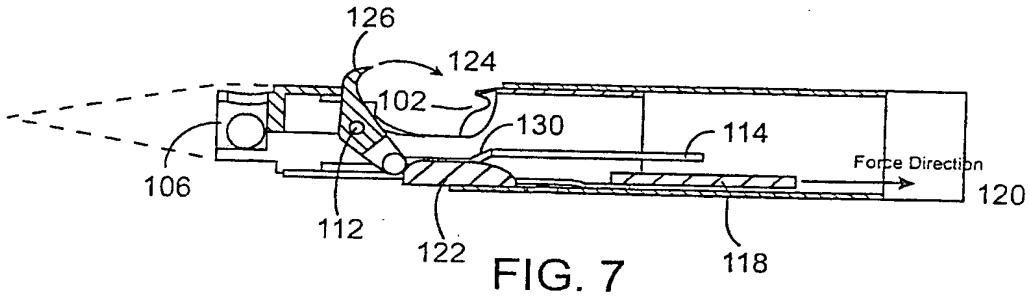



FIG. 7

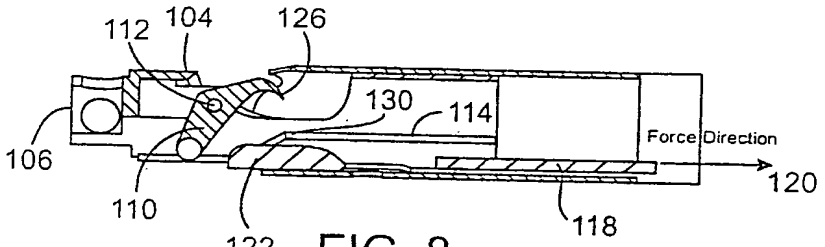



FIG. 8

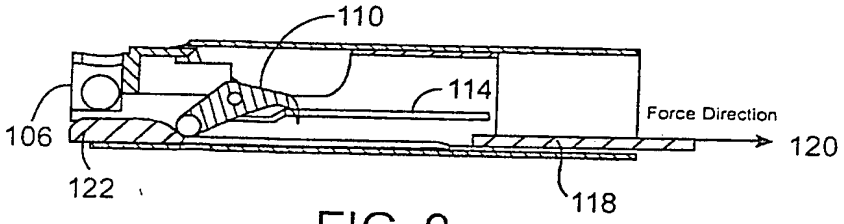



FIG. 9

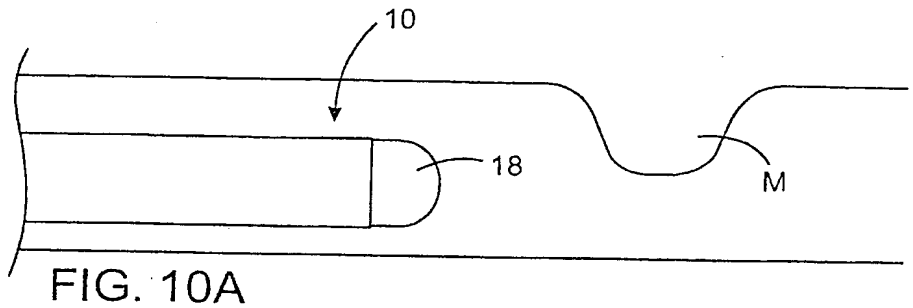



FIG. 10A

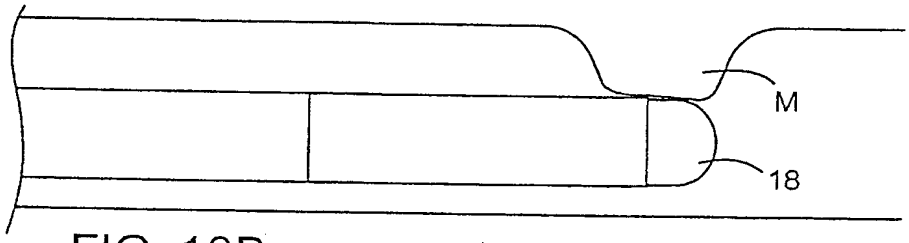



FIG. 10B

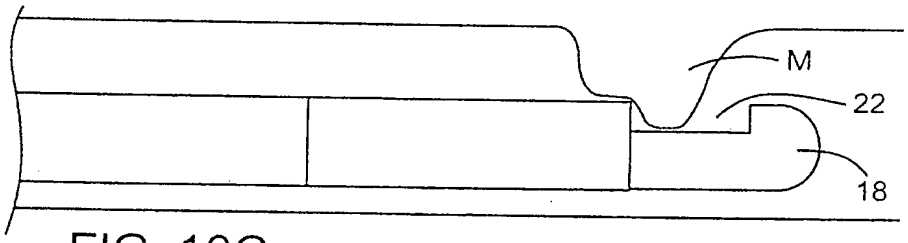



FIG. 10C

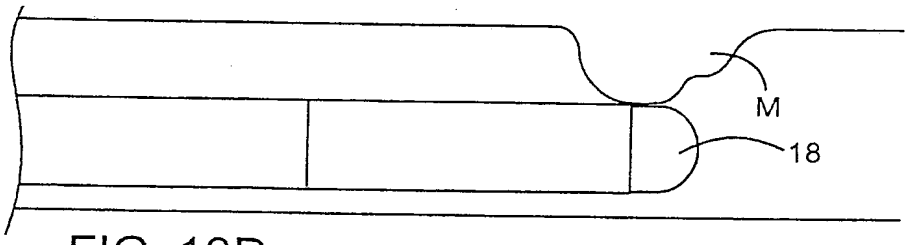



FIG. 10D

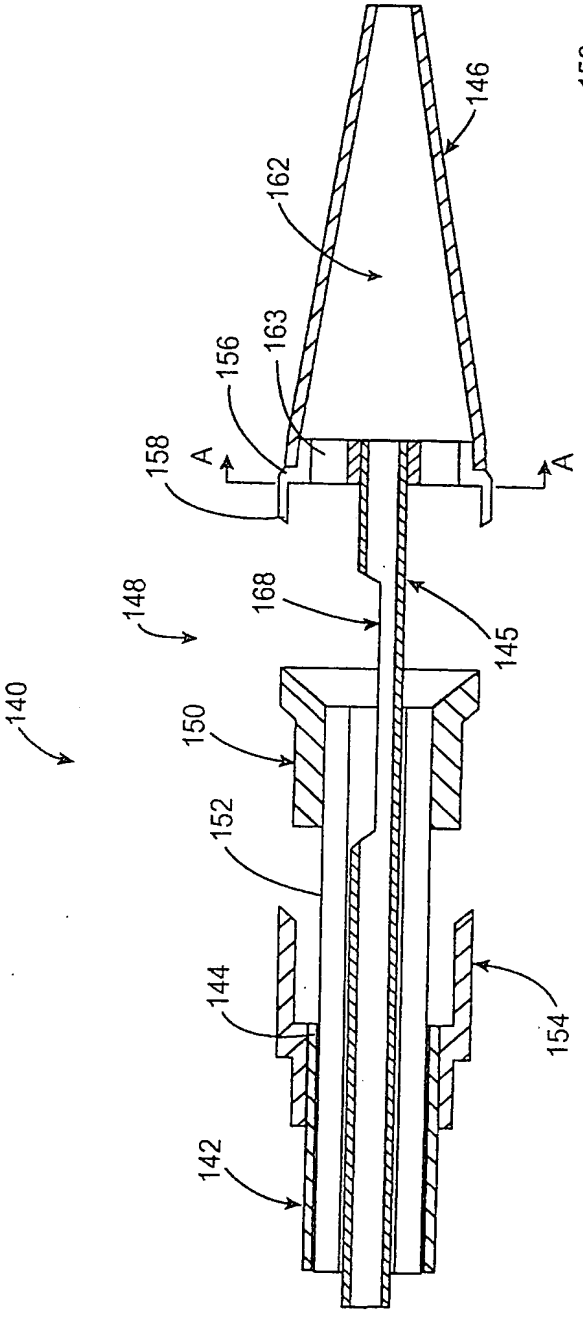



FIG. 11A

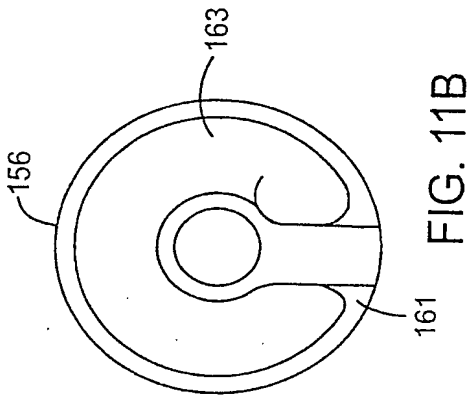



FIG. 11B

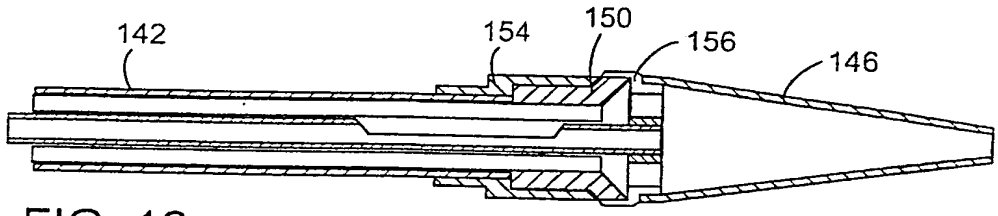



FIG. 12

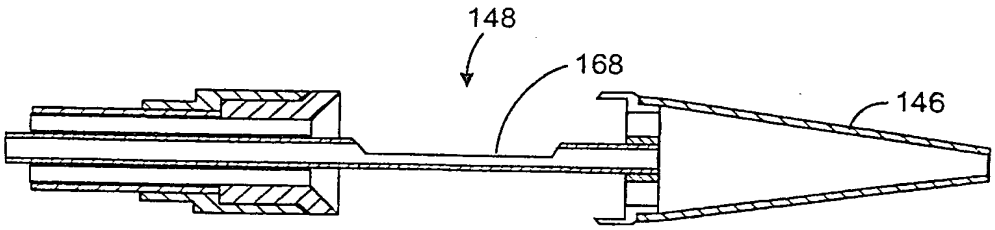



FIG. 13

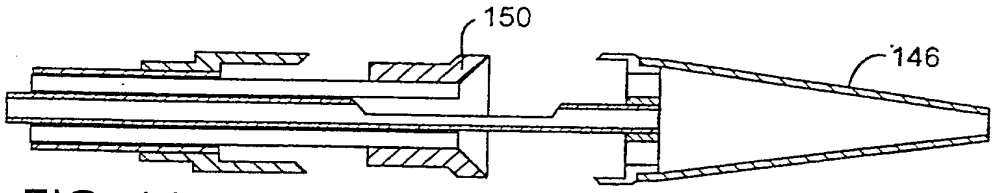



FIG. 14

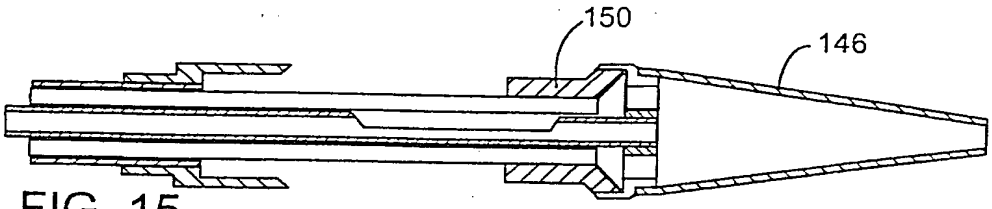



FIG. 15

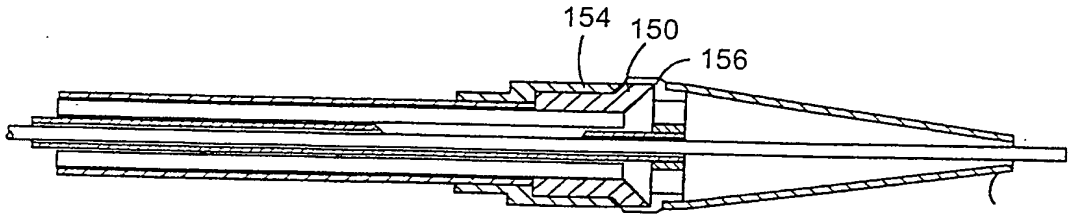



FIG. 16

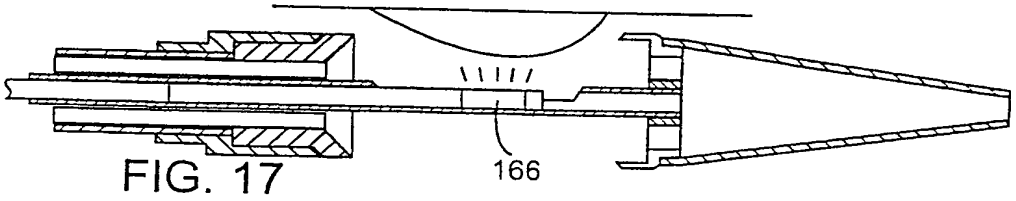



FIG. 17

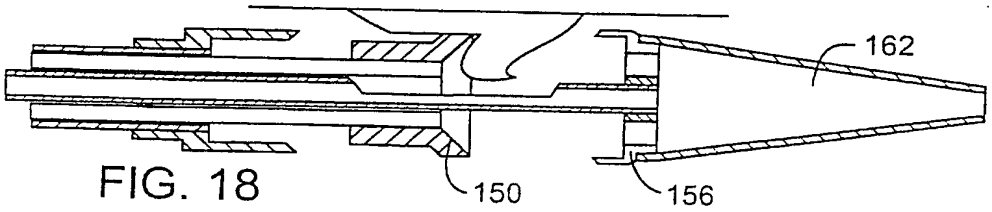



FIG. 18

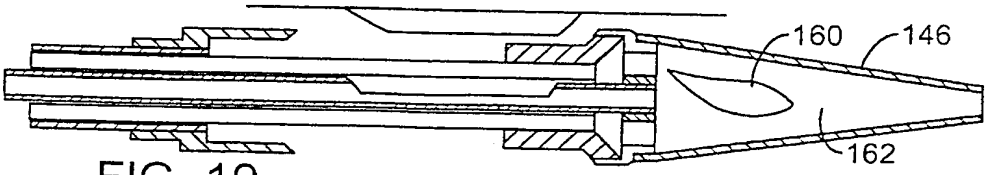



FIG. 19

FIG. 20

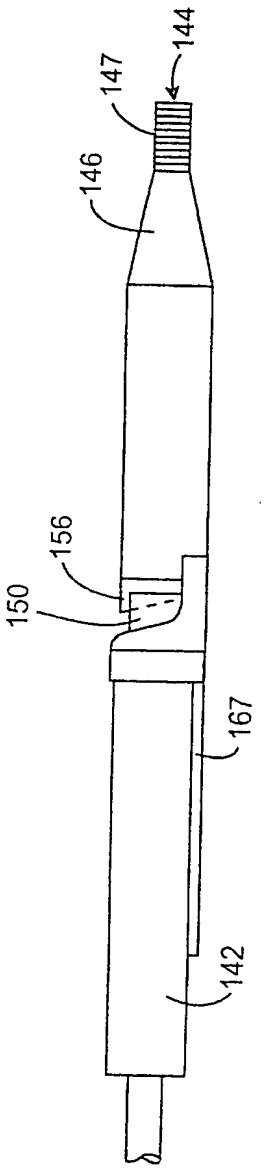



FIG. 21

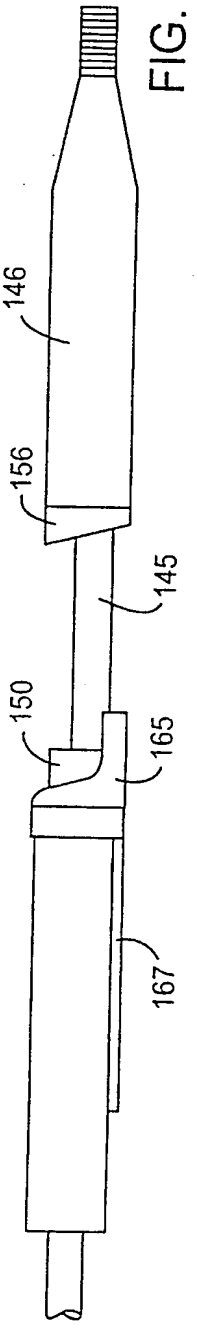
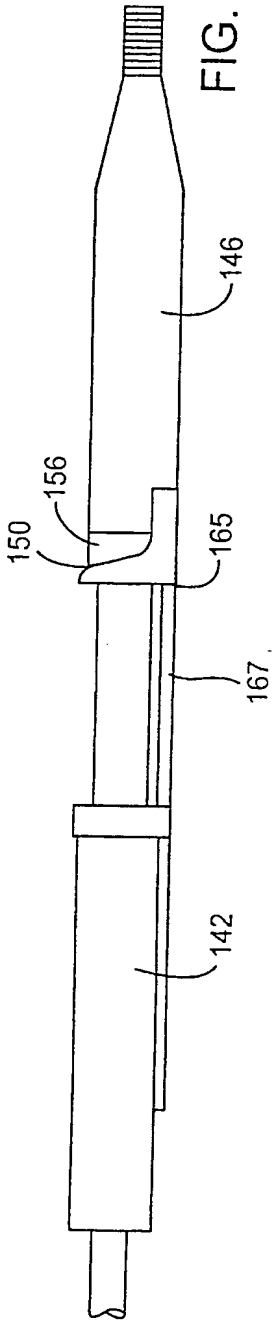



FIG. 22



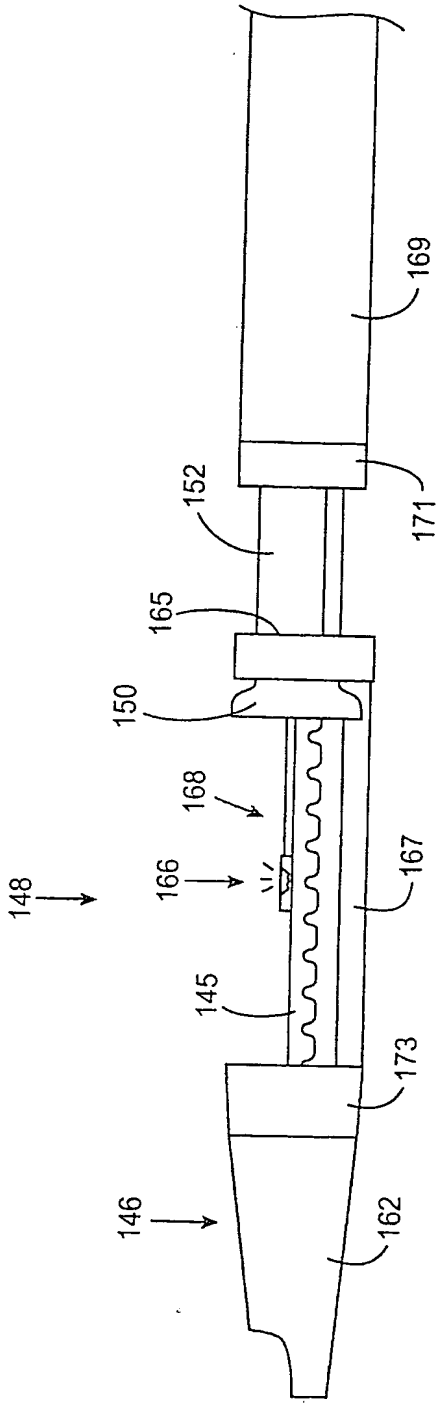



FIG. 23

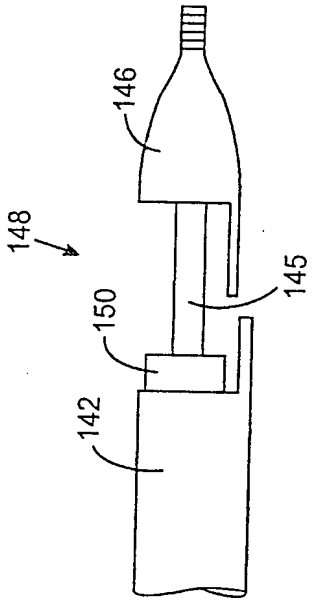



FIG. 24B

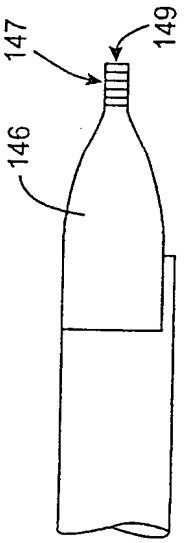



FIG. 24A

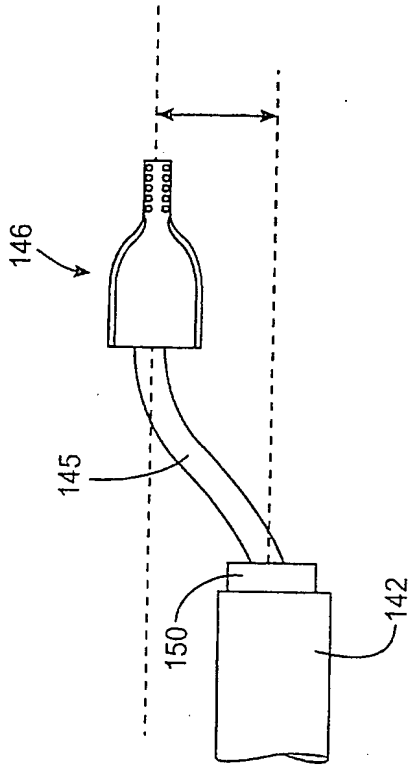



FIG. 30

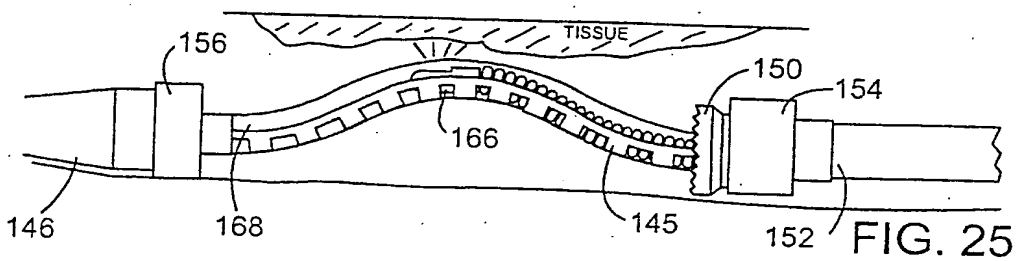



FIG. 25

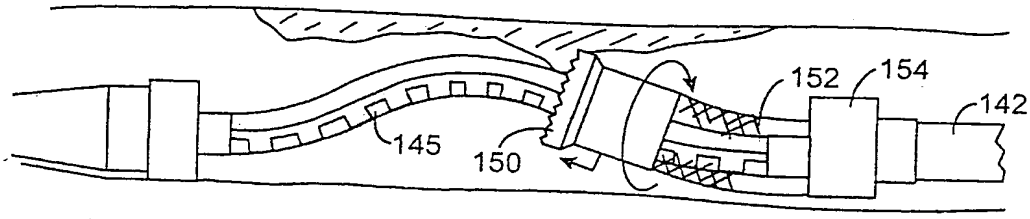



FIG. 26

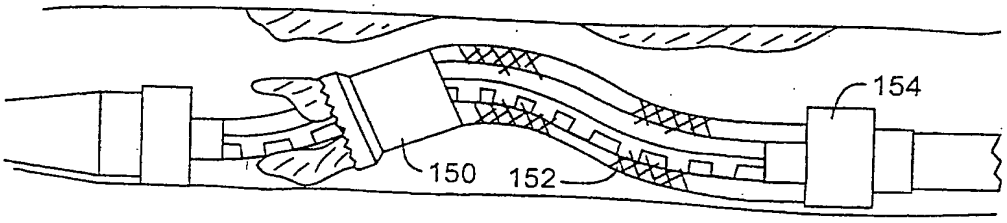



FIG. 27

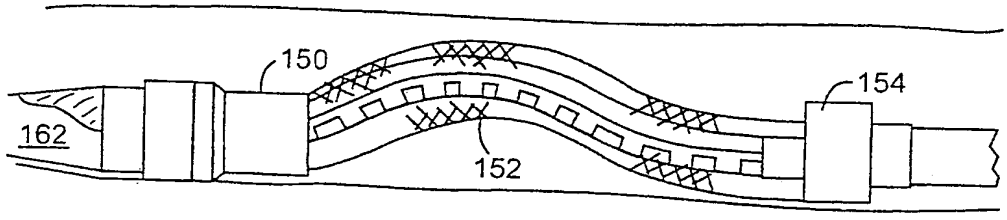



FIG. 28

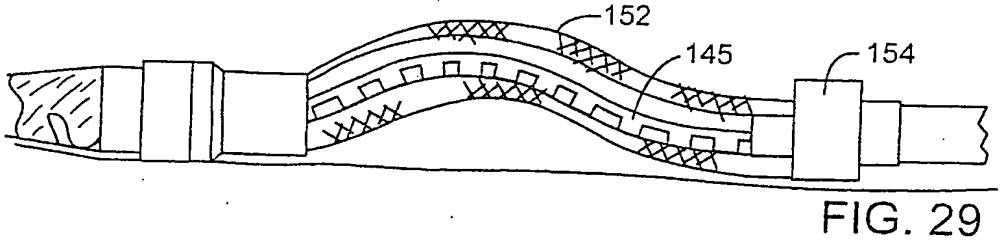



FIG. 29

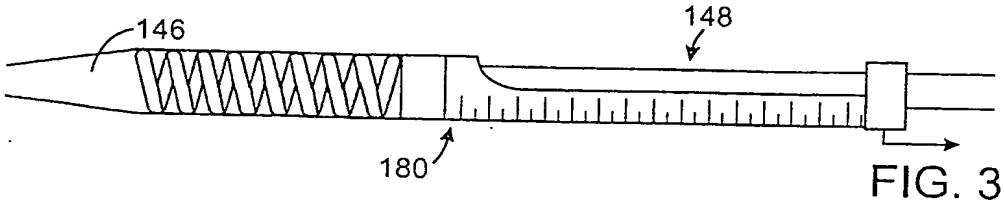



FIG. 31

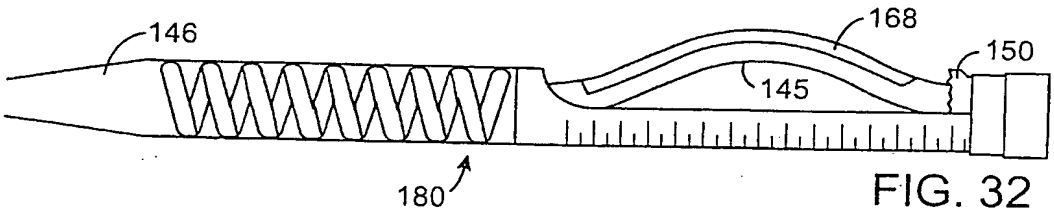



FIG. 32

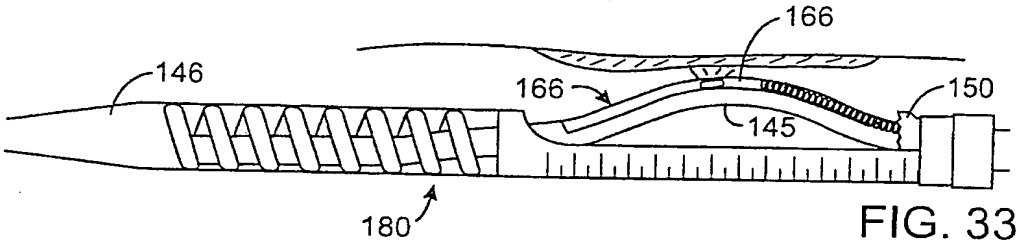



FIG. 33

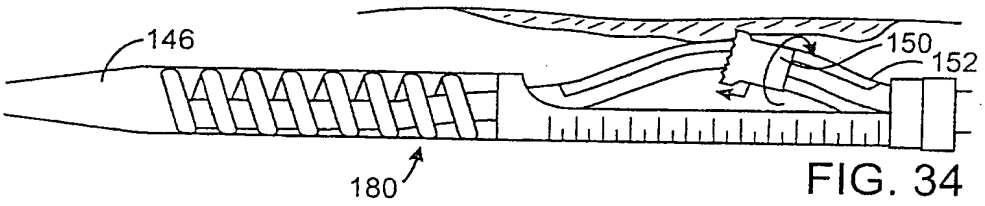



FIG. 34

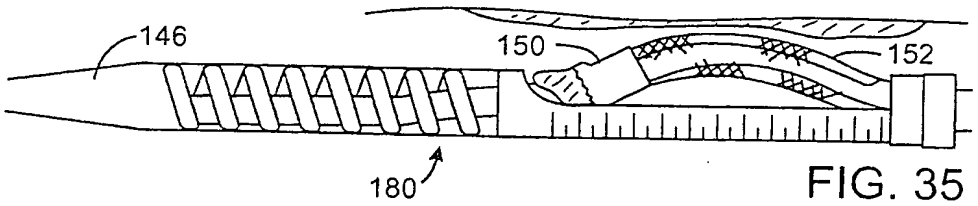



FIG. 35

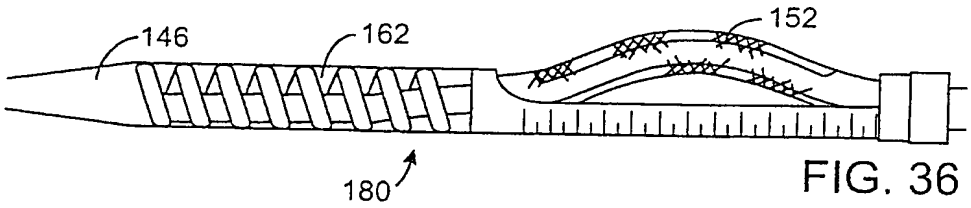



FIG. 36

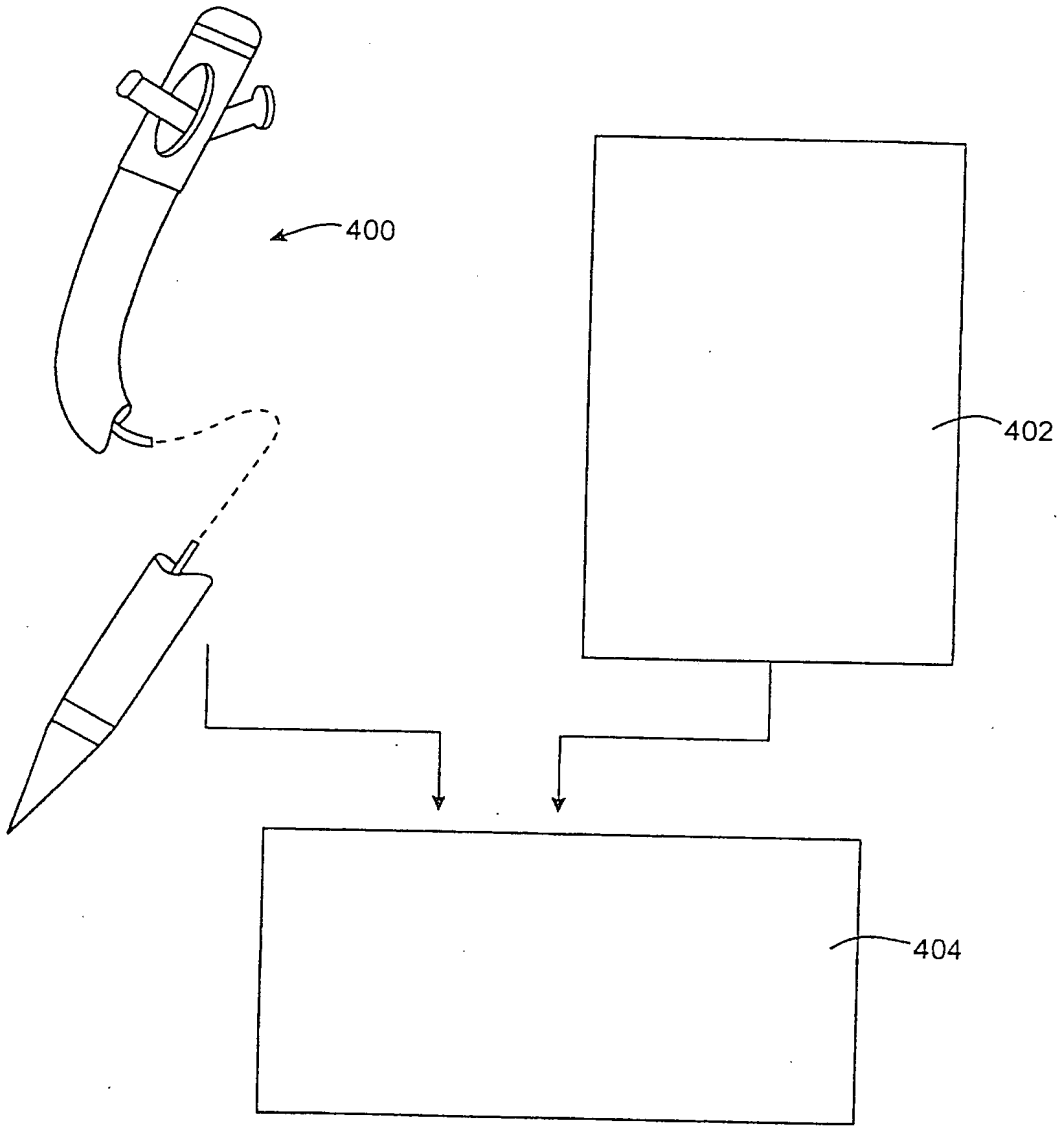



FIG. 37

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/23207

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) :A61B 17/22, 18/18
US CL :128/643.1; 606/6, 10, 159
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 128/653.1; 606/6, 10, 159

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
BRS:
Search Terms: arthe$, matnet$, steerable, navigat$, signal$

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X<br>---<br>Y | US 5,733,296 A (ROGERS et al.) 31 March 1998, whole document. | 1-5, 7-13<br>---<br>14-28 |
| X<br>---<br>Y | US 5,507,292 A (JANG et al.) 16 April 1996, whole document. | 1-9, 11-13<br>---<br>29-40 |
| Y | US 5,634,464 A (JANG et al.) 03 June 1997, whole document. | 21-40 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

| | | | |
|---|---|---|---|
| * | Special categories of cited documents: | "T" | later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| "A" | document defining the general state of the art which is not considered to be of particular relevance | "X" | document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| "E" | earlier document published on or after the international filing date | "Y" | document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "L" | document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "&" | document member of the same patent family |
| "O" | document referring to an oral disclosure, use, exhibition or other means | | |
| "P" | document published prior to the international filing date but later than the priority date claimed | | |

| | |
|---|---|
| Date of the actual completion of the international search<br>29 SEPTEMBER 2000 | Date of mailing of the international search report<br>16 NOV 2000 |
| Name and mailing address of the ISA/US<br>Commissioner of Patents and Trademarks<br>Box PCT<br>Washington, D.C. 20231<br>Facsimile No. (703) 305-3230 | Authorized officer<br>JONATHAN D. GOLDBERG<br>Telephone No. (703) 308-0161 |

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